PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference BCS 02-5002-PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/14840	International filing date *(day/month/year)* 19.12.2003	Priority date *(day/month/year)* 19.12.2002
International Patent Classification (IPC) or both national classification and IPC C12N15/54		
Applicant BAYER CROPSCIENCE GMBH et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05.06.2004	20.04.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Kania, T Telephone No. +49 89 2399-7703

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/14840

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-71 as originally filed

Claims, Numbers

1-14 received on 27.09.2004 with letter of 27.09.2004

Drawings, Sheets

1/11-11/11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: ; which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☒ contained in the international application in written form.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☒ the claims, Nos.: 15-38

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-14
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-14
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations

   see separate sheet

The present International Preliminary Examination Report refers to the following documents cited in the search report:

D1: WO 00/08184 A (HOECHST SCHERING AGREVO GMBH) 17 February 2000 (2000-02-17)

D2: WO 97/20040 A (AMYLOGENE HB ;EK BO (SE); KHOSNOODI JAMSHID (SE); LARSSON CLAS TOM) 5 June 1997 (1997-06-05)

Re Item I: Basis of the report

The amended claims filed with the letter dated 27-09-04 are considered to be allowable as they fulfill the requirements of **Art. 41 PCT**. The examination was based on the amended version of the claims.

Re Item V: Novelty and Inventive step

1. The application relates to methods for the creation of transgenic plants and products thereof which are affected in starch metabolism. In particular, plants are created which express antisense constructs directed to the genes encoding starch synthase SSIII, branching enzyme BEI and branching enzyme BEII. The starch resulting from said plants is particularly characterizd by an increased gel strength as compared to wild type plants.

2. The products and methods according to the present set of claims have not been disclosed in the prior art. Accordingly, the claims are novel **(Article 33(2) PCT)**.

3. D1 is considered as closest prior art for the present application. D1 discloses transgenic plants expressing antisense-constructs of nucleic acid molecules encoding enzymes involved in plant starch metabolism. In particular, antisense plants for both SSIII and BE sequences are disclosed. The latter plants are characterized by a gel strength of their starch which is unaffected with respect to wild-type starch.

   D2 discloses antisense-constructs for the transformation of plants with branching enzyme BEII. The combination of said molecules with antisense molecules directed against other genes involved in starch metabolism (e.g. BEI or SSIII) is suggested.

The present application is distinguished from a mere combination of D1 and D2 by the fact that the gel strength of the present plants is markedly increased. This effect could not be predicted from a combination of D1 and D2 since in D1 gel strength was decreased or at least unaffected in the resulting antisense plants, and D2 does not suggest to combine all three enzymes in order to achieve the said effect.
The increased gel strength of the starch produced by the present plants is therefore acknowledged as a surprising technical effect which could not have been expected by the skilled man from a combination of the teaching of D1 and D2.

In consequence, the present set of claims are inventive **(Article 33(3) PCT)**.

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Patent Claims

1. Plant cell which is genetically modified, the genetic modification leading to the reduction of the activity of one or more SSIII proteins occurring endogenously in the plant cell and to the reduction of the activity of one or more BEI proteins which occur endogenously in the plant cell and to the reduction of the activity of one or more BEII proteins which occur endogenously in the plant cell in comparison to corresponding plant cells, of wild-type plants, which have not been genetically modified, whereas the genetically modified plant cells synthesize a modified starch, which after gelatinization of a 6% suspension in water forms a gel with a gel strength that is increased by at least 300% in comparison with the gel strength of starch extracted from corresponding plant cells, of wild-type plants, which have not been genetically modified.

2. Plant cell according to Claim 1, wherein the genetic modification is the introduction of one or more foreign nucleic acid molecules whose presence and/or expression leads to the reduction of the activity of one or more SSIII and BEI and BEII proteins occurring in the plant cell in comparison with corresponding plant cells, of wild-type plants, which have not been genetically modified.

3. Plant containing plant cells according to one of Claims 1 or 2.

4. Method for generating a genetically modified plant, in which
   a) a plant cell which synthesizes a modified starch, which starch after gelatinization of a 6% suspension in water forms a gel with a gel strength that is increased by at least 300% in comparison with the gel strength of starch extracted from corresponding plant cells, of wild-type plants, which have not been genetically modified, comprising the genetic modification of the plant cell, the genetic modification leading to the reduction of the activity of one or more SSIII proteins which occur endogenously in the plant cell and to the reduction of the activity of one or more BEI proteins which occur endogenously in the plant cell and to the reduction of the activity of one or more BEII proteins which occur endogenously in the plant cell, in

comparison with corresponding plant cells, of wild-type plants, which have not been genetically modified, is generated;

b) a plant is regenerated from, or using, the plant cell generated in accordance with a); and,

c) if appropriate, further plants are generated from the plant generated in accordance with step b).

5. Method for generating a transgenic plant according to Claim 4 which synthesizes a modified starch, in which

a) a plant cell is genetically modified by the introduction of one or more foreign nucleic acid molecules whose presence and/or expression leads to the reduction of the activity of in each case at least one SSIII, BEI and BEII protein in comparison with corresponding wild-type plant cells which have not been genetically modified;

b) a plant is regenerated from, or using, the cell generated in accordance with a); and

c) if appropriate, further plants are generated from the plants generated in accordance with step b).

6. Plant according to Claim 3 or obtainable by the method according to one of Claims 4 or 5, which is a starch-storing plant.

7. Plant according to Claim 6, which is a potato plant.

8. Propagation material of plants according to one of Claims 3, 6 or 7, containing at least one plant cell according to one of Claims 1 or 2.

9. Use of one or more nucleic acid molecules which encode proteins with the enzymatic activity of at least one SSIII, at least one BEI and/or at least one BEII protein or their fragments for the generation of plant cells according to one of Claims 1 or 2 or of plants according to one of Claims 3 or 6 to 7.

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10. Starch which can be obtained from plant cells according to one of Claims 1 or 2 or from a plant according to one of Claims 3, 6 or 7 or from propagation material according to Claim 8.

11. Starch according to Claim 10, which is a potato starch.

12. Method for producing a starch according to one of Claims 10 or 11, comprising the extraction of the starch from a plant according to one of Claims 3, 6 or 7 and/or from starch-storing parts of such a plant and/or from a plant cell according to one of Claims 1 or 2 and/or from propagation material according to Claim 8.

13. Starch according to one of Claims 10 or 11, obtainable by a method according to Claim 12.

14. Method for modifying the starch of a plant, comprising the method for generating a plant according to one of Claims 3, 6 or 7 and obtaining starch from the plant or starch-containing parts thereof.